48. (New) A composition comprising the purified protein or polypeptide of claim 42 and an acceptable carrier.

49. (New) A pharmaceutical composition comprising the purified protein or polypeptide of claim 42 and a pharmaceutically acceptable carrier.

50. (New) A composition comprising the fragment of claim 46 and an acceptable carrier.

51. (New) A pharmaceutical composition comprising the fragment of claim 46 and a pharmaceutically acceptable carrier.

52. (New) A composition comprising the fusion protein of claim 47 and an acceptable carrier.

53. (New) A pharmaceutical composition comprising the fusion protein of claim 47 and a pharmaceutically acceptable carrier.

II. REMARKS

Claims 1-5, 22, 34 and 35 are pending in this application. All claims stand rejected under 35 U.S.C. § 112, first paragraph. It is also alleged that claims 1 and 2 contain new matter.

By this paper claims 2 through 5, 34 and 35, have been canceled without prejudice or disclaimer and claim 1 has been amended. New claims 36 through 53 have been added. The amendments made herein are made in a sincere effort to place the claims in condition for allowance or in better form for consideration on appeal. They were not made earlier as it is Applicant's position that the claims as previously presented disclosed patentable subject matter. Therefore, the amendments are not intended to be a dedication to the public of the subject matter of the previously presented claims.

Support for amended claim 1 and new claim 36 is found in the application papers on page 30, line 7 to page 31, line 26; page 32, lines 8 to 18; page 32, line 33 to page 33, line 13; and page 34, lines 5 to 29. New claim 37 is supported in the application papers on page 17, line 13 through page 18, line 13. Claims 38 through 41 are supported in the application papers on page 23, line 24 to page 24, line 5. Claims 42 through 45 are supported in the application papers on page 37, lines 30 to 33, Figure 1 and Sequence ID No. 2. Support for claim 45 is found in Sequence ID No. 2 and Figure 4E of the application papers. Claim 46 is supported in the application papers as noted for claims 42 through 45 and page 17, line 13 to page 18, line 13. Support for claim 47 is found in the application papers on page 6, lines 22 through 28; page 33, line 36 to page 37, line 33. New claims 48 through 53 are supported on page 23, line 24 through page 24, line 5. Accordingly, an issue of new matter is not raised by these amendments and entry thereof is respectfully requested. Claims 1, 22 and 36 through 53 are presently under examination.

In view of the preceding amendments and the remarks which follow, Applicant respectfully requests reconsideration and withdrawal of the outstanding objections and rejections.

35 U.S.C. § 112, First Paragraph

Claims 1-5, and 22 stand rejected under 35 U.S.C. § 112, first paragraph. More specifically, claims 1 and 2 are rejected as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention at the time of filing. Claims 1-5, and 22 stand rejected as allegedly not enabled by the disclosure. The Office alleged that the specification is enabling only for the human CD40 binding protein of SEQ ID NO:2.

Pursuant to 35 U.S.C. § 112, first paragraph, the specification must convey with reasonably clarity that the Applicant was in possession of the claimed invention at the time of filing. Further, the subject matter of a later added claim need not be described literally or "*in haec verba*" in order for the specification to satisfy the description requirement. *In re Wright,* 9 USPQ2d 1649 (Fed. Cir. 1989). In the subject application, claim 1 is objected to as allegedly including new matter in the form of the phrase "and does not specifically bind to a homologous

cell-surface receptor of the tumor necrosis family." Similarly, the phrase "comprising the C-terminal half" is alleged to be new matter in claim 2.

Applicant submits that the specification plainly establishes that Applicant was in possession of the subject matter of claims 1 and 2 at the time of filing. For instance, in addition to the pages pointed out in the Amendment filed on June 28, 1996, Applicant directs the Examiner's attention to page 31, lines 20 to 26 and Figure 1 where in the specification describes and demonstrates how the novel protein of the claimed invention does not specifically bind to tumor necrosis factor cell-surface receptors such as Fas and TNF. Thus, as of the filing date, Applicant was in possession of the invention recited in claim 1.

Similarly, the specification intended to include the C-terminal half of the CD40bp recited in claim 2. On page 6, lines 6 to 13, Applicant describes how the subject invention includes fragments of the protein shown in SEQ ID NO:2 which have the ability to bind the cytoplasmic domain of the CD40 receptor using, for example, the *in vitro* binding assay described in Experiment II. Moreover, as previously noted, Applicant actually identified CD40bp proteins which encoded only the C-terminal half of CD40bp and still bound to the cytoplasmic region of the CD40 receptor. (See, page 37, lines 25 to 33). However, to advance prosecution, claim 2 has been canceled without prejudice or disclaimer.

Claims 1 to 5, and 22 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being enabled by the specification. Applicant traverses this rejection and again submit that the disclosure enables claims drawn to a purified CD40bp. Under 35 U.S.C. § 112, first paragraph, the specification must teach one of skill in the art how to make and use the claimed invention. Not everything necessary to practice the invention need be disclosed in the specification. In fact, what is well-known in the art is preferably omitted from the specification. *Hybritech Inc., v. Monoclonal Antibodies, Inc.,* 231 USPQ 81, 94 (Fed. Cir. 1986), *cert denied,* 480 U.S. 947 (1987).

Claim 1 had been amended herein to recite a purified CD40bp having an apparent molecular weight of about 64 kD on SDS-PAGE under reducing conditions and which specifically binds the cytoplasmic domain of CD40. Example 1 of the application papers show that nine clones which encode such a protein were isolated. The protein was termed CD40bp.

In other portions of the specification, Applicant defines CD40bp in both structural and functional terms. On page 5, lines 24 to 26, the specification indicates that CD40bp are novel proteins, defined by their unique ability to bind to the cytoplasmic domain of the CD40 receptor. The specification further indicates that the CD40bp have an apparent molecular weight of about 64 kD (page 6); and have a RING finger domain, a coiled-coil domain, and a C-terminal half which binds to the CD40 receptor (page 37). Accordingly, the specification sets forth both physical characterization and functional characteristics of the claimed proteins.

Applicant also submits that there is sufficient guidance in the specification as to how CD40bp could be isolated in other mammals. The specification teaches on page 8, lines 17 to 30 and page 11, lines 6 to 23 how homologous proteins may be isolated from various species by methods known in the art. Thus, a skilled artisan could, without undue experimentation, clone and sequence CD40bp in other species.

Furthermore, the specification provides the embodiment of a CD40bp fragment (the C-terminal region) which binds to the CD40 receptor. In addition, the specification teaches how other fragments that are isolated using well known techniques can be assayed using a simple *in vitro* system to assay binding to the cytoplasmic domain of CD40. In view of these teachings, it would not require undue experimentation to make fragments falling within the scope of the claims drawn to CD40bp fragments and test them for binding activity. Without conceding the correctness of the Office's position, however, the claims have been amended and new claims have been added to more clearly define the fragments of the invention.

With respect to claim 22, the Office argues that the claims to a dominant inhibitory fragment are not enabled by the specification. Applicant respectfully traverses. It is well within the skill of the ordinary artisan to make various polypeptide fragments using the guidance provided in the specification and art-recognized methods. The skilled artisan can then assay the fragments for their ability to bind to the receptor using the assays defined in the specification on page 25, lines 18 through 33.

In view of the foregoing, withdrawal of the outstanding rejections are respectfully requested.

Information Disclosure Statement

Attached to this response are two international patent publications for placement into the application file. The publication of the patent applications occurred after the filing date of the subject application.

III. CONCLUSION

If a telephone interview would be of assistance in advancing prosecution of the subject application, the Examiner is invited to telephone the undersigned at the number provided below. In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: February 3, 1997

Respectfully submitted,

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U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES	Translation NO
	1.	06.06.96	WO 96/16665	PCT				
	2.	07.12.95	WO 95/33051	PCT				

no copies

OTHER DOCUMENTS *(including author, title, Date, Pertinent Pages, Etc.)*

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